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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,204	02/16/2004	Itzhak Bentwich	050992.0201.CPUS03	2203

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ROSETTA-GENOMICS

c/o PSWS

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SUITE 1000

KANSAS CITY, MO 64112

EXAMINER

WOLLENBERGER, LOUIS V

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/708,204

Applicant(s)

BENTWICH, ITZHAK

Examiner

Louis V. Wollenberger

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1–10, 17–29, drawn to a bioinformatically detectable isolated oligonucleotide, classified in class 536, subclass 24.5, for example. Election of this group requires the further election of a single nucleotide sequence (i.e., a single SEQ ID NO:) from claims 1-6, 17, 20-23, and 25; and a single target gene from claims 2, 5, and 17, as explained below.
- II. Claim 30, drawn to a method for bioinformatic detection of microRNA, classified in class 435, subclass 6, for example.

Claims 11–16 are not included in either of the above groups since it is unclear what Applicant is seeking to claim in each of claims 11–16; thus, the Examiner is unable to ascertain which group(s) claims 11–16 belong to.

Appropriate correction is required.

Applicant is advised that any amendments to the claims, including claims 11–16, may necessitate further restriction, depending on the amendment made to the claims.

Nevertheless, regardless of the current status of claims 11-16, Applicant is required to make a provisional election with or without traverse of one of the groups set forth above, as well as any further elections therein, to which the application will be restricted if no generic claim is held allowable.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product oligonucleotides can be used in a materially different process. For example, the product oligonucleotides can be used as RNAi or antisense molecules to inhibit the expression of specific target genes in cells and/or organisms, which does not require bioinformatically detecting the oligonucleotides as in Group II.

In addition, searching and examining each of these groups in a single application would present a serious burden on the examiner, since each group would require different keyword searches (i.e., different fields of search) and different considerations of the patent and non-patent literature with regard to novelty, obviousness, written description, and enablement.

Therefore, because these inventions are distinct for the reasons given above, and the searches required for each are divergent and not coextensive, and because a search and examination of all of the Inventions in a single application would present a serious burden on the Examiner, restriction for examination purposes as indicated is proper.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found

allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Restriction to a single nucleotide sequence

Should applicant elect to prosecute Group I, this Group is subject to further restriction as follows.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences recited in claims 1-6, 17, 20-23, and 25 are subject to restriction since they are not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

The instant claims specifically claim over two thousand different nucleotide sequences which presumably target different genes or different regions of a gene related to Alzheimer's Disease.

Although the oligonucleotides claimed may target and modulate expression of genes that are functionally related, the instant sequences are considered to be structurally and functionally independent and distinct since each sequence has a unique nucleotide sequence, each sequence

targets a different gene and/or different nucleic acid sequence, and, absent evidence to the contrary, each oligo, upon binding to its target, is expected to functionally modulate (increase or decrease) the expression of that target to varying degrees.

As such, the Markush/genus of sequences in the instant claims are not considered to constitute a proper genus, and are therefore subject to restriction.

Furthermore, a search of more than one (1) of the sequences claimed in the instant claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. In view of the foregoing, one (1) nucleotide sequence is considered to be a reasonable number of sequences for examination.

Accordingly, applicants are required to elect one (1) sequence from the instant claims for prosecution on the merits with Group I. Note that this is not a species election.

Although this restriction requires election of a single nucleotide sequence, applicant should be aware that the Office's computer search systems will automatically search both the elected sequence and its complement. If the instantly claimed SEQ ID NOS: are sequences defined as sense sequences that have a counterpart antisense sequence, applicants are welcome to make their election as a sense/antisense sequence pair reciting a sense sequence and its corresponding antisense sequence as a search of the sense sequence of such a pair will automatically search the antisense sequence of the pair.

In the event of rejoinder of product and process claims, applicants are reminded that the process claim identified above depending from the product claims identified above must recite the same SEQ ID No to remain consonant with this restriction requirement.

Applicants are advised that the election of a single nucleotide sequence should be consistent with and correspond to the election of the single target gene, as set forth in the requirement below.

Restriction to a Single Target Gene

In addition to electing a single nucleotide sequence (see above), should applicants elect to prosecute Group I, Applicants are further required to elect a single target gene from claim 2, 5, and 17.

The instant claims recite a plurality of different target genes, which may be targeted by a variety of different bioinformatically detectable oligonucleotides.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, these target genes are subject to restriction since they are not considered to be a proper genus/Markush. See MPEP 803.02 (PRACTICE RE MARKUSH-TYPE CLAIMS).

In the instant case, the target genes do not appear to share a substantial structural feature disclosed as being essential to a common utility. The target genes recited appear to be structurally and functionally distinct, having different nucleotide sequences and giving rise to different proteins.

Furthermore, searching all these target genes in a single application would impose a serious burden on the examiner since a search of each of these genes would require different key word searches of the patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform an examination of all claims to all these genes in a single application.

Accordingly, Applicant is required to elect one (1) target gene from the instant claims for prosecution on the merits with the elected group. Note that this is not a species election.

In the event of rejoinder of product and process claims, applicants are reminded that the process claim identified above depending from the product claims identified above must recite the same gene to remain consonant with this restriction requirement.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.


Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571)272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Louis Wollenberger
Examiner, Art Unit 1635
September 7, 2006



SEAN MCGARRY
PRIMARY EXAMINER
1635